Package leaflet: Information for the user
Humalog® 200 units/ml, solution for injection in pre-filled pen
insulin lispro

Lilly

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Humalog 200 units/ml KwikPen™ is and what it is used for
2. What you need to know before you use Humalog 200 units/ml KwikPen
3. How to use Humalog 200 units/ml KwikPen
4. Possible side effects
5. How to store Humalog 200 units/ml KwikPen
6. Contents of the pack and other information

1. What Humalog 200 units/ml KwikPen is and what it is used for

Humalog 200 units/ml KwikPen is used to treat diabetes. Humalog works more quickly than normal human insulin because insulin lispro has been changed slightly in comparison to human insulin. Insulin lispro is closely related to human insulin which is a natural hormone made by the pancreas.

You get diabetes if your pancreas does not make enough insulin to control the level of glucose in your blood. Humalog is a substitute for your own insulin and is used to control glucose in the long term. It works very quickly and lasts a shorter time than soluble insulin (2 to 5 hours). You should normally use Humalog within 15 minutes of a meal.

Your doctor may tell you to use Humalog 200 units/ml KwikPen as well as a longer-acting insulin. Each kind of insulin comes with another patient information leaflet to tell you about it. Do not change your insulin unless your doctor tells you to.

Humalog 200 units/ml KwikPen should be reserved for the treatment of adults with diabetes requiring daily doses of more than 20 units of rapid-acting insulin.

2. What you need to know before you use Humalog 200 units/ml KwikPen

Do NOT use Humalog 200 units/ml KwikPen
- if you are **allergic** to insulin lispro or any of the other ingredients of this medicine (listed in section 6).
- if you think **hypoglycaemia** (low blood sugar) is starting. Further in this leaflet it tells you how to deal with mild hypoglycaemia (see section 3: If you take more Humalog than you need).

Warnings and precautions
- **The Humalog 200 units/ml solution for injection in your pre-filled pen (the KwikPen) should ONLY be injected with this pre-filled pen. Do not transfer the insulin lispro from your**

Humalog 200 units/ml KwikPen to a syringe. The markings on the insulin syringe will not measure your dose correctly. A severe overdose can result, causing low blood sugar which may put your life in danger. Do not transfer insulin from your Humalog 200 units/ml KwikPen to any other insulin delivery devices like insulin infusion pumps.

- **Do NOT mix the Humalog 200 units/ml solution for injection in your pre-filled pen (the KwikPen) with any other insulin or any other medicine.** The Humalog 200 units/ml solution for injection should not be diluted.
- If your blood sugar levels are well controlled by your current insulin therapy, you may not feel the warning symptoms when your blood sugar is falling too low. Warning signs are listed in section 4 of this leaflet. You must think carefully about when to have your meals, how often to exercise and how much to do. You must also keep a close watch on your blood sugar levels by testing your blood glucose often.
- A few people who have had hypoglycaemia after switching from animal insulin to human insulin have reported that the early warning symptoms were less obvious or different. If you often have hypoglycaemia or have difficulty recognising it, please discuss this with your doctor.
- If you answer YES to any of the following questions, tell your doctor, pharmacist or diabetes nurse
  - Have you recently become ill?
  - Do you have trouble with your kidneys or liver?
  - Are you exercising more than usual?
- You should also tell your doctor, pharmacist or diabetes nurse if you are planning to go abroad. The time difference between countries may mean that you have to have your injections and meals at different times from when you are at home.
- Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with pioglitazone and insulin experienced the development of heart failure. Inform your doctor as soon as possible, if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).

Other medicines and Humalog 200 units/ml KwikPen

Your insulin needs may change if you are taking

- the contraceptive pill,
- steroids,
- thyroid hormone replacement therapy,
- oral hypoglycaemics (e.g. metformin, acarbose, sulphonylurea agents, pioglitazone, empagliflozin, DPP-4-inhibitors like sitagliptin or saxagliptine),
- acetyl salicylic acid,
- sulpha antibiotics,
- somatostatin analogues (such as octreotide, used to treat an uncommon condition in which you make too much growth hormone),
- "$beta_2$ stimulants"such as salbutamol or terbutaline to treat asthma, or ritodrine used to stop premature labour,
- beta-blockers – to treat high blood pressure, or
- some antidepressants (monoamine oxidase inhibitors or selective serotonin reuptake inhibitors),
- danazol (medicine acting on ovulation),
- some angiotensin converting (ACE) inhibitors, used to treat certain heart conditions or high blood pressure (for example captopril, enalapril), and
- specific medicines to treat high blood pressure, kidney damage due to diabetes, and some heart problems (angiotensin II receptor blockers).

Please tell your doctor, if you are taking, have recently taken or might take any other medicines (see also section "Warnings and precautions").

Humalog with alcohol

Your blood sugar levels may either rise or fall if you drink alcohol. Therefore the amount of insulin needed may change.

Pregnancy and breast-feeding
Are you pregnant or thinking about becoming pregnant, or are you breast-feeding? The amount of insulin you need usually falls during the first three months of pregnancy and increases for the remaining six months. If you are breast-feeding, you may need to alter your insulin intake or diet. Ask your doctor for advice.

Driving and using machines
Your ability to concentrate and react may be reduced if you have hypoglycaemia. Please keep this possible problem in mind in all situations where you might put yourself and others at risk (e.g. driving a car or using machines). You should contact your doctor about the advisability of driving if you have:
- frequent episodes of hypoglycaemia
- reduced or absent warning signs of hypoglycaemia

3. How to use Humalog 200 units/ml KwikPen

Always check the pack and the label of the pre-filled pen for the name and type of the insulin when you get it from your pharmacy. Make sure you get the Humalog 200 units/ml KwikPen that your doctor has told you to use.

Always use this medicine exactly as your doctor has told you. You should check with your doctor if you are not sure.

Humalog 200 units/ml KwikPen is for patients taking more than 20 units of rapid-acting insulin a day.

Do not transfer insulin from your Humalog 200 units/ml KwikPen to a syringe. The markings on the insulin syringe will not measure your dose correctly. A severe overdose can result, causing low blood sugar which may put your life in danger.

Do not use Humalog 200 units/ml KwikPen solution for injection in an insulin infusion pump.

Dosage
- You should normally inject Humalog within 15 minutes of a meal. If you need to, you can inject soon after a meal. But your doctor will have told you exactly how much to use, when to use it, and how often. These instructions are only for you. Follow them exactly and visit your diabetes clinic regularly.
- If you change the type of insulin you use (for example from a human or animal insulin to a Humalog product), you may have to take more or less than before. This might just be for the first injection or it may be a gradual change over several weeks or months.
- Inject Humalog under the skin (subcutaneously).

Preparing Humalog 200 units/ml KwikPen
- Humalog is already dissolved in water, so you do not need to mix it. But you must use it **only** if it looks like water. It must be clear, have no colour and no solid pieces in it. Check each time you inject yourself.

Getting the KwikPen ready to use (Please see user manual)
- First wash your hands.
- Read the instructions on how to use your pre-filled insulin pen. Please follow the instructions carefully. Here are some reminders.

- Use a clean needle. (Needles are not included).
- Prime your KwikPen before each use. This checks that insulin comes out and clears the air bubbles from your KwikPen. There may still be some small air bubbles left in the pen - these are harmless. But if the air bubbles are too large it may affect the insulin dose.

Injecting Humalog
- Before you make an injection, clean your skin as you have been instructed. Inject under the skin, as you were taught. After your injection, leave the needle in the skin for five seconds to make sure you have taken the whole dose. Do not rub the area you have just injected. Make sure you inject at least half an inch (1 cm) from the last injection and that you 'rotate' the places you inject, as you have been taught. It doesn't matter which injection site you use, either upper arm, thigh, buttock or abdomen, your Humalog injection will still work quicker than soluble human insulin.
- Do not inject Humalog 200 units/ml KwikPen solution for injection directly into a vein (intravenously).

After injecting
- As soon as you have done the injection, unscrew the needle from the KwikPen using the outer needle cap. This will keep the insulin sterile and stop it leaking. It also stops air entering the pen and your needle clogging. **Do not share your needles**. Do not share your pen. Replace the cap on your pen.

Further injections
- Every time you use a KwikPen you must use a new needle. Before every injection, clear any air bubbles. You can see how much insulin is left by holding the KwikPen with the needle pointing up.
- Once the KwikPen is empty, do not use it again. Please get rid of it carefully - your pharmacist or diabetes nurse will tell you how to do this.

If you take more Humalog than you need
If you take more Humalog than you need, a low blood sugar may occur. Check your blood sugar.
If your blood sugar is low **(mild hypoglycaemia)**, eat glucose tablets, sugar or drink a sugary drink. Then eat fruit, biscuits, or a sandwich, as your doctor has advised you and have some rest. This will often get you over mild hypoglycaemia or a minor insulin overdose. If you get worse and your breathing is shallow and your skin gets pale, tell your doctor at once. A glucagon injection can treat quite severe hypoglycaemia. Eat glucose or sugar after the glucagon injection. If you do not respond to glucagon, you will have to go to hospital. Ask your doctor to tell you about glucagon.

If you forget to use Humalog
If you take less Humalog than you need, a high blood sugar may occur. Check your blood sugar.

If hypoglycaemia (low blood sugar) or hyperglycaemia (high blood sugar) is not treated, they can be very serious and cause headaches, feeling sick (nausea), being sick (vomiting), loss of fluids (dehydration), unconsciousness, coma or even death (see section 4 "Possible side effects").

Three simple steps to avoid hypoglycaemia or hyperglycaemia are:
- Always keep spare syringes and a spare vial of Humalog 100units/ml, or a spare pen and cartridges, in case you lose your KwikPen or it gets damaged.
- Always carry something to show you are diabetic.
- Always carry sugar with you.

If you stop using Humalog.
If you take less Humalog than you need, a high blood sugar may occur. Do not change your insulin unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Severe allergy is rare (may affect up to 1 in 1,000 people). The symptoms are as follows:
- rash over the whole body
- difficulty in breathing
- wheezing
- blood pressure dropping
- heart beating fast
- sweating

If you think you are having this sort of insulin allergy with Humalog, contact a doctor at once.

Local allergy is common (may affect up to 1 in 10 people). Some people get redness, swelling or itching around the area of the insulin injection. This usually clears up in anything from a few days to a few weeks. If this happens to you, tell your doctor.

Lipodystrophy (thickening or pitting of the skin) is uncommon (may affect up to 1 in 100 people). If you notice your skin thickening or pitting at the injection site, tell your doctor.

Oedema (e.g. swelling in arms, ankles; fluid retention) has been reported, particularly at the start of insulin therapy or during a change in therapy to improve control of your blood glucose.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **Ireland:** HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, website: www.hpra.ie, e-mail: medsafety@hpra.ie, or **United Kingdom:**
Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

Common problems of diabetes

Hypoglycaemia
Hypoglycaemia (low blood sugar) means there is not enough sugar in the blood. This can be caused if:
- you take too much Humalog or other insulin;
- you miss or delay meals or change your diet;
- you exercise or work too hard just before or after a meal;
- you have an infection or illness (especially diarrhoea or vomiting);
- there is a change in your need for insulin; or
- you have trouble with your kidneys or liver which gets worse.

Alcohol and some medicines can affect your blood sugar levels (see section 2).

The first symptoms of low blood sugar usually come on quickly and include the following:
- tiredness
- nervousness or shakiness
- headache
- rapid heartbeat
- feeling sick
- cold sweat

While you are not confident about recognising your warning symptoms, avoid situations such as driving a car, in which you or others would be put at risk by hypoglycaemia.

Hyperglycaemia and diabetic ketoacidosis
Hyperglycaemia (too much sugar in the blood) means that your body does not have enough insulin. Hyperglycaemia can be brought about by:
- not taking your Humalog or other insulin;

- taking less insulin than your doctor tells you to;
- eating a lot more than your diet allows; or
- fever, infection or emotional stress.

Hyperglycaemia can lead to diabetic ketoacidosis. The first symptoms come on slowly over many hours or days. The symptoms include the following:

- feeling sleepy
- flushed face
- thirst
- no appetite
- fruity smell on the breath
- feeling or being sick

Severe symptoms are heavy breathing and a rapid pulse. **Get medical help immediately.**

Illness
If you are ill, especially if you feel sick or are sick, the amount of insulin you need may change. **Even when you are not eating normally, you still need insulin.** Test your urine or blood, follow your 'sick rules', and tell your doctor.

5. How to store Humalog 200 units/ml KwikPen

Keep this medicine out of the sight and reach of children.

Do not use Humalog **200 units/ml** KwikPen after the expiry date which is stated on the label and the carton. The expiry date refers to the last day of that month.

Before the first use store your Humalog **200 units/ml** KwikPen in a refrigerator (2°C – 8°C). Do not freeze.

Keep your Humalog **200 units/ml** KwikPen in use at room temperature (15° - 30°C) and discard after 28 days. Do not put it near heat or in the sun. Do not keep the KwikPen that you are using in the fridge. The KwikPen should not be stored with the needle attached.

Do not use Humalog **200 units/ml** KwikPen, if the solution is coloured or it has solid pieces in it. You must use it **only** if it looks like water. Check this each time you inject yourself.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Humalog 200 units/ml KwikPen solution for injection contains
- The active substance is insulin lispro. Each ml of solution contains 200 units (U) of insulin lispro. Each pre-filled pen (3 ml) contains 600 units (U) of insulin lispro.
- The other ingredients are metacresol, glycerol, trometamol, zinc oxide and water for injection. Sodium hydroxide or hydrochloric acid may have been used to adjust the acidity.

What Humalog 200 units/ml KwikPen looks like and contents of the pack
Humalog 200 units/ml KwikPen, solution for injection is a sterile, clear, colourless, aqueous solution and contains 200 units of insulin lispro in each millilitre (200 units/ml) solution for injection. Each Humalog **200 units/ml** KwikPen contains 600 units (3 millilitres). The Humalog **200 units/ml** KwikPen comes in a pack of 1, 2 or 5 pre-filled pens or multipacks of 2 x 5 pre-filled pens. Not all pack sizes may be marketed. The KwikPen simply has a built in cartridge. When the pre-filled pen is empty you cannot use it again.

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu/.